

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of)	
)	
ECUMED HEALTH GROUP)	ADMINISTRATIVE COMPLAINT
a corporation,)	<u>FOR CIVIL MONEY PENALTY</u>
)	
and)	
)	
AMADOR REYES,)	FDA Docket: 2004H-0322
JUAN C. CARRAI,)	
RICHARD W. STONE, M.D., and)	
ERLINDA E. ENRIQUEZ, M.D.,)	
individuals.)	
_____)	

COMPLAINANT'S WITNESS LIST

Complainant, Center for Devices and Radiological Health,
Food and Drug Administration (FDA), submits the following list of
witnesses:

MICHAEL P. DIVINE, M.S., Compliance Expert for the
Inspection and Compliance Branch, Division of Mammography Quality
and Radiation Programs, Office of Health and Industry Programs,
Center for Devices and Radiological Health, United States Food
and Drug Administration, 1350 Piccard Drive, Rockville, MD 20850.
Mr. Divine is expected to testify regarding the inspection,
compliance, and certification program for mammography facilities
under the Mammography Quality Standards Act of 1992, 42
U.S.C. § 263b. Mr. Divine is also expected to provide testimony
regarding the accreditation and certification history of
Respondents Ecumed Health Group ("EHG"), Amador Reyes, Juan C.
Carrai, Richard W. Stone, M.D., and Erlinda E. Enriquez, M.D.,

2004H-0322

LST /


including communications between Respondents, FDA, and the American College of Radiology.

TIMOTHY J. COUZINS, Compliance Officer, Florida District Office, United States Food and Drug Administration, 555 Winderly Pl., Suite 200, Maitland, FL 32751. Mr. Couzins is expected to testify regarding inspections of the EHG facility and the documents and other information collected during those inspections.

D. JANNETH CAYCEDO, Investigator, Boca Raton Field Office, United States Food and Drug Administration, 1499 W. Palmetto Park Rd., Boca Raton, FL 33486. Ms. Caycedo is expected to testify regarding inspections of the EHG facility and documents and other information collected during those inspections.

PRISCILLA F. BUTLER, M.S., Senior Director, Breast Imaging Accreditation Programs, Department of Quality Safety, the American College of Radiology ("ACR"), 1891 Preston White Drive, Reston, VA 20191. Ms. Butler is expected to testify regarding ACR's accreditation program and communications between ACR and respondents.

Respectfully submitted,


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CERTIFICATE OF SERVICE


I certify under the penalty of perjury that on this 20th day of May, 2005, I served a copy of "Complainant's Witness List" via facsimile and regular U.S. mail on the following:

Mario R. Delgado
Attorney for Ecumed Health
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